OIP.E Im 99°C

1614

Practioner's Docket No.

2605/102

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent application	
ofInv	ventor(s)
for	
Title o	of invention
	OR
In re application of: Toshio Miyata	
Application No.: 10/009,877 Group No Filed: November 13, 2001 Examiner For: Blood Carbonyl Compound-Trapping Agent	: Not Yet Assigned
Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450 TRANSMITTAL OF SURDI EMENTAL I	NFORMATION DISCLOSURE STATEMENT
WITHIN THREE M	IONTHS OF FILING OR ICE ACTION (37 C.F.R. SECTION 1.97(b))
CERTIFICATE OF MAILING/TRA	NSMISSION (37 C.F.R. SECTION 1.8(a))
I hereby certify that, on the date shown below, this correspond	dence is being:
MAILING	FACSIMILE
[x] deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450	[] transmitted by facsimile to the Patent and Trademark Office.
Date:March 10, 2004	Signature Bark J Court
	Barbara J. Carter, Ph.D. (type or print name of person vertifying)

 $(Transmittal\ of\ Information\ Disclosure\ Statement\ Within\ Three\ Months\ of\ Filing\ or\ Before\ Mailing\ of\ First\ Office\ Action-page$

1 of 3)

- NOTE:" An information disclosure statement shall be considered by the Office if filed by the applicant: (1) within three months of the filing date of a national application; (2) within three months of the date of entry of the national stage as set forth in section 1.491 in an international application; or (3) before the mailing date of a first Office action on the merits, whichever event occurs last." 37 C.F.R. section 1.97(b).
- NOTE: The "filing date of a national application" under 37 C.F.R. section 1.97(b) has two possible meanings. Where the filing is a direct one to the United States Patent & Trademark office, the filing is defined in 37 C.F.R. section 1.53(b) as "the date on which: (1) A specification containing a description pursuant to section 1.71 and at least one claim pursuant to section 1.75; and (2) any drawing required by section 1.81(a), are filed in the Patent and Trademark Office in the name of the actual inventor or inventors as required by section 1.41." 37 C.F.R. section 1.97(b)(1). On the other hand, an international application that enters the national stage occurs when the applicant has filed the documents and fees required by 35 U.S.C. section 371(c) within the periods set forth in section 1.494 or section 1.495. 35 U.S.C. section 371(c) requires the filing of the following: (1) the basic national fee; (2) a copy of the international application, unless already sent by the International Bureau, and optionally an English translation if filed in another language; and, also optionally (3) amendments under PCT Article 19, with a translation into English if made in another language; (4) an oath or declaration; and (5) a translation into English of any annexes to the international preliminary examination report, if such annexes were made in another language. The optional items must be submitted later, with surcharges. 37 C.F.R. section 1.97(b)(2).

IDENTIFICATION OF TIME OF FILING THE ACCOMPANYING SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

The information disclosure statement submitted herewith is being filed within three months of the filing date of the application or date of entry into the national stage of an international application or before the mailing date of a first Office action on the merits, whichever event occurs last. 37 C.F.R. section 1.97(b).

- NOTE: "No certification or fee is due when the filing is made within the above time period. It is advisable to ensure that no Office action has been mailed if the disclosure statement is delayed until after three months from filing."
- NOTE: "An information disclosure statement will be considered to have been filed on the day it was received in the Office, or on an earlier date of a mailing if accompanied by a properly executed certificate of mailing under 37 C.F.R. 1.8, or Express Mail certificate under 37 C.F.R. 1.10. An office action is mailed on the date indicated in the Office action." Notice of April 20, 1992 (1138 O.G. 37-41, 39).
- NOTE: "The term hational application' includes continuing applications (continuations, divisions, continuations-in-part) so three-months will be measured from the actual filing date of an application as opposed [sic] to the effective date of a continuing application." Notice of April 20, 1992 (1138 O.G. 37-41, 39).
- NOTE: "An action on the merits means an action which treats the patentability of the claims in an application, as opposed to only formal or procedural requirements. An action on the merits would, for example, contain a rejection or indication of allowability of a claim or claims rather than just a restriction requirement (37 C.F.R. section 1.142) or just a requirement for additional fees to have a claim considered (37 C.F.R. section 1.16(d)). Thus, if an application was filed on Jan. 1 and the first Office action on the merits was not mailed until six months later on July 1, the examiner would be required to consider any proper information disclosure statement filed prior to July 1." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

WARNING:"A petition for suspension of action to allow applicant time to submit an information disclosure statement will be denied as failing to present good and sufficient reasons, since 37 C.F.R. section 1.97 provides adequate recourse for the timely submission of prior art for consideration by the examiner." Notice of July 6, 1992 (1141 O.G. 63).

SIGNATURE OF PRACTIVIONER

Reg. No. 52,703

Tel. No.: (617) 443-9292

Customer No.: 002101

02605/00102 298489.1

Barbara J. Carter, Ph.D. (type or print name of practitioner)

125 Summer Street, 11th Floor

P.O. Address

Boston, MA 02110

SECTION 2. FORMS PTO/SB/08A and 08B (formerly Form PTO-1449)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:

Toshio Miyata

Attorney Docket:

2605/102

Serial No:

10/009,877

Art Group Unit:

1614

Date Filed:

November 13, 2001

Examiner Name:

Not Yet Assigned.

Invention:

Blood Carbonyl Compound-Trapping Agent

LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

	U.S. PATENT DOCUMENTS								
Examiner Initials	Reference Number	Document Number	Issue Date	Inventor	Class/Subclass				
	DP	US5,128,360	07/07/1992	Cerami, et al.	514/400				
	DQ	US5,827,820	10/27/1998	duMoulin, et al.	514/2				
	DR US5,855,882		55,855,882 01/05/1999		424/94.61				
	DS	US5,861,238	01/19/1999	Li, et al.	435/2				
	DT	US5,891,341	04/06/1999	Li, et al.	210/646				
	DU	US5,962,245	10/05/1999	Li, et al.	435/18				

			FOREIGN PATENT	DOCUME	NTS	
Exam. Initials	Ref. No.	Country Code	Doc. No.	Public. Date	Patentee or Applicant	Class/Subclass
	DV	JP	5-105633, A and corresponding English translation.	4/27/93	Sato, T.	A61K 31/70
	DW	JP	4-187158, A and corresponding English abstract	7/3/92	Masuda, T., et al.	A61M 1/28
	DX	JP	8-131542, A and corresponding English translation	5/28/96	Izumi, G., et al.	A61M 1/14
	DY	JP	6-507822, A See Ref. DQ for corresponding US Application	9/8/94	duMoulin, A., et al.	A61M 1/28
	DZ JP 63-19149, A (We Could Not Obtain any English Translation or a Concise English Explanation of this Document)		1/26/88	Suzuki, T, et al.	A61 J 1/00	
	EA	WO	93/19792 (Ref. DQ is a continuation of this application)	10/14/93	duMoulin A, et al.	A61M 1/28

	OTHER DOCUMENTS							
Exam. Initials								
	ЕВ	Tanaka Y, et al.	Inhibitory Effect of Metformin on Formation of Advanced Glycation End Products, <i>Current Therapeutic Research</i> , Vol. 58, No. 10 (10/1997) pp. 693-697.					

ADEMARK OF	EC	Lo TWC, et al.	Binding and Modification of Proteins by Methylglyoxal Under Physiological Conditions, <i>J Biol Chem</i> , Vol. 269, No. 51 (12/23/1994): pp. 32299-32305
ADEMA	ED	Niquette, P., et al.	Backwashing First-Stage Sand-BAC Filters, J Am Water Works Assoc, Vol. 90, Issue 1 (January, 1998), pp 86-97
	EF	Combet ,S., et al.	Vascular Proliferation and Enhanced Expression of Endothelial Nitric Oxide Synthase in Human Peritoneum Exposed to Long-Term Peritoneal Dialysis, J Am Soc Nephrol, 11:717-728 (2000)
	EG	Combet, S., et al.	Regulation of Aquaporin-1 and Nitric Oxide Synthase Isoforms in a Rat Model of Acute Peritonitis, <i>J Am Soc Nephrol</i> , 10:2185-2196 (1999)
	ЕН	Faller, B.	Amino Acid-Based Peritoneal Dialysis Solutions, <i>Kidney Intl</i> , Vol. 50, Suppl. 56 (1996), pps. S-81-S-85.
	EI	Miyata, T., et al.	Mechanism of the Inhibitory Effect of OPB-9195 [(±) -2- Isopropylidenehydrazono-4-oxo-thiazolidin-5-ylacetanilide] on Advanced Glycation End Product and Advanced Lipoxidation End Product Formation, J Am Soc Nephrol, 11:1719-1725 (2000).
	EJ	Miyata, T., et al.	Accumulation of Carbonyls Accelerates the Formation of Pentosidine, an Advanced Glycation End Product: Carbonyl Stress in Uremia, <i>J. Am Soc Nephrol</i> , 9:2349-2356 (1998).
	EK	Miyata, T., et al.	Autoxidation Products of Both Carbohydrates and Lipids are Increased in Uremic Plasma: Is there Oxidative Stress in Uremia?, <i>Kidney Intl</i> , Vol. 54 (1998), pp. 1290-1295.
	EL	Miyata, T., et al.	Alterations in Nonenzymatic Biochemistry in Uremia: Origin and Significance of "Carbonyl Stress" in Long-Term Uremic Complications, Kidney Intl, Vol. 55 (1999) pp. 389-399.
	EM	Nakayama, M., et al.	Immunohistochemical Detection of Advanced Glycosylation End-Products in the Peritoneum and its Possible Pathophysiological Role in CAPD, <i>Kidney Intl</i> , Vol. 51 (1997) pp. 182-186.
	EN	Wilkie, ME, et al.	Polyglucose Solutions in CAPD, <i>Perit Dial Intl</i> , Vol. 17, (1997), pp. S47-S50.
	ЕО	Yamada, K., et al.	Immunohistochemical Study of Human Advanced Glycosylation End- Products (AGE) in Chronic Renal Failure, <i>Clin Nephrol</i> , Vol. 42, No. 6 (1994) pp. 354-361.

Examiner Signature:
Date Considered:
EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Section 6. Copies of Listed Information Items Accompanying This Statement

NOTE: 37 C.F.R. section 1.98(a)(2) requires that any information disclosure statement filed under section 1.97 shall include:

"A legible copy of: (1) Each U.S. and foreign patent; (ii) Each publication or that portion which caused it to be listed; and (iii) All other information or that portion which caused it to be listed, except that no copy of a U.S. patent application need be included . . ."

NOTE: The wording in section 1.98(a)(2)(iii) makes it clear that the requirement to submit a copy of each item of information listed in an information disclosure statement does not apply to the citation of a U.S. patent application. Notice of January 9, 1992, 1135 O.G. 13-25, at 14.

Legible copies of all items listed in Forms PTO/SB/08A and 08B (substitute for Form PTO-1449) accompany this information statement.

(complete the following, if applicable)

[]Exception(s) to above:
[]Items in prior application, from which an earlier filing date is claimed for this application, as identified in Section 4.
[]Cumulative patents or publications identified in Section 5.

Section 8. Translation(s) of Non-English Language Documents

NOTE: "If a written English language translation of a non-English language document, or portion thereof, is within the possession, custody or control of, or is readily available to any individual designated in section 1.56(c), a copy of the translation shall accompany the statement." 37 C.F.R. section 1.98(c).

NOTE: "The Office does not intend to require translations unless they have been reduced to writing and are actually translations of what is contained in the non-English language information. Applicants should note, however, that most examiners do not have the ability to understand information which is not in English and that the Office will not routinely translate information submitted in a non-English language. The examiner will consider the information insofar as it is understood on its face, e.g., drawings, chemical formulas, English language abstracts, but will not have the information translated unless it appears to be necessary to do so. Applicants are required to aid the examiner by complying with the requirements for a concise explanation in section 1.98(a)(3) for information submitted in a non-English language." Notice of January 9, 1992, 1135 O.G. 13-25, at 21.

NOTE: "The examiner will indicate that the non-English language information has been considered in the same manner as consideration is indicated for information submitted in English." Notice of April 20, 1992 (1138 O.G. 37-41, 41).

[x] Submitted herewith is an English translation of the following foreign language patents, publications or information or of those portions of those patents, publications or information considered to be material:

DV	JP	5-105633, A and corresponding English translation.	4/27/93	Sato, T.	A61K 31/70
DW	JP	4-187158, A and corresponding English abstract	7/3/92	Masuda, T., et al.	A61M 1/28
DX	JP	8-131542, A and corresponding English translation	5/28/96	Izumi, G., et al.	A61M 1/14
DY	JP	6-507822, A See Ref. DQ for corresponding US Application	9/8/94	duMoulin, A., et al.	A61M 1/28
EA	wo	93/19792 (Ref. DQ is a continuation of this application)	10/14/93	duMoulin A, et al.	A61M 1/28

(complete the following, if applicable)

X	No English	language t	translations	of the	foreign	language	patents,	publications	or	information	or
	parts thereo	f are readily	y available,	except	for those	e listed abo	ove.				

IJ	The follow	ving foreign	ı langua	age docu	iments sub	omitted a	are	believed	to be	the equi	valen	t or
	substantial	equivalent	of the	English	language	docume	ents	identified	below	, which	are	also
	submitted h	nerewith.										

Section 10. Identification of Person(s) Making This Supplemental Information Disclosure Statement

The person making this certification is	
(check ed	ach applicable item)
(a) []the inventor(s) who signs below	
	SIGNATURE OF INVENTOR
	(type name of inventor who is signing)
(b) []an individual associated with the find 1.56(c))	ling and prosecution of this application (37 C.F.R. section
	SIGNATURE OF INVENTOR
	(type name of inventor who is signing)
(c) [x] the practitioner who signs below or	n the basis of the information:
(check ed	ach applicable item)
[] supplied by the inventor(s).
	dual associated with the filing and prosecution of this C.F.R. section 1.56(c)).
[x] in the practitioner's file.	
	Bab 1 Cent
Reg. No.: 52,703	SIGNATURE OF PRACTITIONER
	Barbara J. Carter, Ph.D.
Tel. No.: (617) 443-9292	(type or print name of practitioner)
	125 Summer Street, 11 th Floor
Customer No.: 002101	P.O. Address
	Boston, MA 02110
02605/00102 298490.1	